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Attachment D

510(k) Summary

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510(k) Summary

1. **Applicant Contact:**

Trudy D. Estridge, PhD
Director, Regulatory Affairs
Angiotech
Dulles Gateway Center
13921 Park Center Road, Suite 100
Herndon, VA 20171 USA
CA voice: 510-742-5301
VA voice: 703-796-8927
Fax: 703-673-0061

Date Prepared: December 13, 2007

2. **Name of Device:** Skater® Biliary Drainage Catheter
   Common Name: Biliary Catheter
   Classification Name: Catheter, Biliary, Diagnostic
   Regulation 21 CFR 876.5010 – Product code FGE

3. **Identification of device(s) to which the submitted claims equivalence:**

Angiotech, Skater® Biliary Drainage Catheter, K070610 is being referred to as the predicate device for the intended use of the device.

Medical Device Technologies, Inc., CanaliZer Hydrophilic Guide Wire, K050873 is being referred to as the predicate for the use of only the coating.

4. **Device Description:**
The Skater® Biliary Drainage Catheter is a polyurethane catheter with SLIP-COAT™, a lubricious hydrophilic coating.. The catheter comes in a pigtail-loop, locking-type, end configuration with drainage holes. The catheters are provided in 8 French, 10 French, and 12 French sizes with a length of 40 cm. Accessories include a metal stiffening cannula, a plastic stiffening cannula, and a standard luer locking hub.

5. **Intended Use of Device:**
The Skater® Biliary Drainage Catheter is indicated for percutaneous biliary drainage.

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6. Technological characteristics of the device in comparison to those of the predicate device(s)

Feature/ Technological Characteristics	Skater® Biliary Drainage Catheter (Predicate Device) K070610	CanaliZer Hydrophilic Guide Wire* K050873	Skater® Biliary Drainage Catheter (New Device)
Intended Use	Intended for percutaneous biliary drainage.	N/A*	Intended for percutaneous biliary drainage.
Characteristics	Drainage catheter with metal and plastic stiffening cannula and female/male luer hub (adapter)	N/A*	Drainage catheter with metal and plastic stiffening cannula and female/male luer hub (adapter). The tubing has the option of having a radiopaque marker band.
Sizes (French)	8, 10, 12	N/A*	8, 10, 12
Length (cm)	40 cm from hub to distal tip in curved position	N/A*	40 cm from hub to distal tip in curved position
Lumens	One	N/A*	One
Distal End Configuration	8 Fr. – 12 side drainage holes and one end drainage hole, pigtail. 10 and 12 Fr. – 11 side drainage hoes and one end drainage hole, pigtail.	N/A*	8 Fr. – 12 side drainage holes and one end drainage hole, pigtail. 10 and 12 Fr. – 11 side drainage hoes and one end drainage hole, pigtail.
Intended anatomical location of distal end	Biliary system	N/A*	Biliary system
Proximal end configuration	Female/male luer hub (adapter) and clip	N/A*	Female/male luer hub (adapter) and clip
Materials	Polyurethane	Polyurethane	Polyurethane
Coating	Hydrophilic	Hydrophilic	Hydrophilic

***Predicate is only for slip coat being applied to polyurethane material. It is not applicable to form, fit or function of the device. This is an acceptable coating.**

7. Safety and Performance:

The Skater® Biliary Drainage Catheter has been tested and compared to the predicate device. Testing included dimensional inspection, process performance qualification, biocompatibility, aging, LAL, bioburden, and EO/EC residual. All data gathered demonstrates that the Skater® Biliary Drainage Catheter is comparable to the predicate devices.

The results of *in vitro* bench tests and biocompatibility testing demonstrate the safety and effectiveness of the Skater® Biliary Drainage Catheter.

8. Conclusion

Based on the design, material, function and intended use discussed herein, Angiotech believes the Skater® Biliary Drainage Catheter is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2008

Trudy D. Estridge, Ph.D.
Director of Regulatory Affairs
Angiotech
13921 Park Center Road, STE 100
HERNDON VA 21071

Re: K073672
Trade/Device Name: Skater® Biliary Drainage Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: December 13, 2007
Received: December 27, 2007

Dear Dr. Estridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Attachment B

Indications for Use Statement

510(k) Number (if known): K073672

Device Name: **Skater® Biliary Drainage Catheter**

Indications for Use:

The Skater® Biliary Drainage Catheter is indicated for percutaneous biliary drainage.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ (Part 21 CFR 801.109) OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073672